IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC,	)	
Plaintiffs,	)	C.A. No. 07-792 (GMS)
v.	)	**JURY TRIAL DEMANDED**
APOTEX INC. and APOTEX CORP.,	)	
Defendants.	)	

OPENING BRIEF IN SUPPORT OF MOTION TO TRANSFER IN FAVOR OF PENDING FLORIDA JURISDICTION, OR IN THE ALTERNATIVE TO STAY THE DELAWARE LITIGATION

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Dated: January 24, 2008
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Defendants Apotex Inc. and Apotex Corp. (collectively "Apotex") request that the Court transfer this litigation, pursuant to 28 U.S.C. § 1404 (a), to the Southern District of Florida where an identical lawsuit already is underway and trial is scheduled to occur there less than nine months from now.

Plaintiffs Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively "Sanofi") sued Apotex in the Southern District of Florida, Apotex answered that complaint and counterclaimed against Sanofi in Florida, and Sanofi has replied to Apotex's Florida counterclaim. *See Sanofi's Florida Complaint* attached hereto as Exhibit A and *Answer of Apotex Inc. and Apotex Corp. to Complaint, Affirmative Defenses and Amended Counterclaims* attached hereto as Exhibit B.

The Florida Court already has set a discovery schedule and has scheduled trial for a two-week period beginning on **October 6, 2008**. *See* January 22, 2008 Revised Scheduling Order (Judge Moreno) attached hereto as Exhibit C.[1] The parties in Florida already have had their Fed. R. Civ. P. 26(f) conference, exchanged Fed. R. Civ. P. 26(a)(1) disclosures, and discovery has begun in the case. By contrast, other than initial pleadings, the Delaware action has not yet begun. There has been no Fed. R. Civ. P. 26(f) conference. No discovery has been served. No trial date has been set.

One of the primary purposes of the *Hatch-Waxman* Act is to expedite resolution of patent disputes involving drug products in order to facilitate the public's access to less expensive generic drugs. *See In re Barr Labs., Inc.* 930 F.2d 72, 76 (D.C. Cir. 1991) (explaining that

[1] The Florida Court's original scheduling order (dated January 3, 2008) had set trial for May 2008. The revised scheduling order was entered in response to Sanofi's Motion to Continue Pretrial Deadlines and Trial, wherein Sanofi sought to delay the trial date until **September 2009**. At the time the Florida Court entered its revised scheduling order, Sanofi also had filed a motion in the Florida Court seeking to transfer that case to Delaware or to stay it, which motion Apotex is opposing. Although Sanofi's motion is still pending before the Florida Court, that Court was aware that Sanofi was seeking transfer of that action to Delaware when it entered its revised scheduling order.

Congress enacted the Hatch-Waxman Act for to "get generic drugs into the hands of patients at reasonable prices – fast."); 21 U.S.C. § 355(j)(5)(B)(iii) (parties required to "reasonably cooperate in **expediting** the action." (emphasis added)). Transferring this case to Florida will accomplish that goal. It is unlikely the parties will proceed at anything near this speed in the District of Delaware.

Florida also is a much more convenient and logical forum for this action. One of the Defendants, Apotex Corporation, which will market and sell the allegedly infringing drug product, has its headquarters in Florida. (McIntire Decl. at ¶4[2]). Sanofi has alleged that Apotex Corp. is "jointly and severally liable" for Apotex, Inc.'s alleged infringement of the '491 patent, and has further accused Apotex Corp. of participating in, aiding and abetting, inducing and contributing to "Apotex Inc.'s submission of ANDA 79-013 and its §505(j)(2)(A)(vii)(IV) allegation to the FDA." Del. Compl. ¶15 (Dkt.1). While Apotex denies these allegations (or even that they state a claim for infringement), the situs of these alleged acts, and any related Apotex Corp. documents and witnesses, necessarily would be Florida, where Apotex Corp. is located.

None of the parties have active operations in Delaware. Apotex Corp.'s operations are located in Florida. Apotex, Inc., whose act of filing an abbreviated new drug application ("ANDA") to market a generic version of an approved drug is the alleged act of infringement under 35 U.S.C. § 271(e)(2), is a Canadian company whose operations are based in Canada. (Tao Decl. at ¶¶4, 6[3]). According to Sanofi's complaint, Sanofi-Aventis U.S., which presently markets the drug at issue here, is located in New Jersey. Del. Compl. ¶2. Its parent, Sanofi-

[2] All references to "McIntire Decl." are to the Declaration of Tammy McIntire, submitted concurrently herewith.

[3] All references to "Tao Decl." are to the Declaration of Jeremy Tao, submitted concurrently herewith.

Aventis, which purports to own the patents in suit, is located in France. Del. Compl. ¶1. None of the acts accused of infringement here have any connection to Delaware. None of the documents necessary as evidence for this matter are located in Delaware. ((McIntire Decl. at ¶7; Tao Decl. at ¶9). None of the potential witnesses are located in Delaware. (McIntire Decl. at ¶ 6; Tao Decl. at ¶8).

The only connection Delaware has to this matter is the incorporation of Apotex Corp. and Sanofi-Aventis U.S. L.L.C., which courts have recognized is not a dispositive factor in the 28 U.S.C § 1404 analysis – indeed state of incorporation is not listed in § 1404 as a factor to consider in determining an appropriate forum. 28 U.S.C. § 1404; *see also Mentor Graphics Corp. v. Quickturn Design Systems, Inc.*, 77 F. Supp. 2d 505, 509 n. 6 (D. Del. 1999) ("Although the court does not mean to suggest that a defendant's state of incorporation is irrelevant to a venue transfer inquiry, it is certainly not dispositive.").

Accordingly, the Court should transfer this litigation to Florida, or in the alternative, the Court should stay this litigation until a resolution is reached in Florida.

BACKGROUND

Sanofi brought this lawsuit under the Hatch-Waxman Act alleging Apotex infringes one of their patents under 35 U.S.C. § 271(e)(2) by submitting an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA"). The Hatch-Waxman Act was enacted to promote and expedite the public's access to lower priced generic drugs. H.R. Rep. No. 98-547, 98th Cong., 2d sess., pt. 1 at p. 28, *reprinted in* 1984 U.S.C.C.A.C. 2647.

I. STATUTORY AND REGULATORY BACKGROUND

To obtain FDA approval to sell a drug that has not been previously approved, a company generally must file a new drug application ("NDA"). 21 U.S.C. § 355(b). The Hatch-Waxman Act requires NDA holders, such as Sanofi, to submit a list of all patents that cover their approved drugs. 21 U.S.C. § 355(b)(1). These patents are published in the FDA's "Approved Drug Products with Therapeutic Equivalence Evaluations" also known as "the Orange Book."

Generic companies wishing to market a drug covered by a NDA are permitted to file an ANDA, which substitutes bioequivalence data for the safety and efficacy studies in a NDA. In cases where the generic manufacturer seeks approval to market the generic pharmaceuticals before the expiration of the patents, the generic must submit a "paragraph IV" certification to the FDA that the applicable patents listed in the Orange Book are invalid or will not be infringed by the manufacture, use, or sale of the drug covered by the ANDA. 21 C.F.R. § 314.94(a)(12)(i)(A). Additionally, the generic must notify the brand manufacturer in writing, per a Paragraph IV letter, that such certification was made. 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. 314.95(c)(6).

The submission of a paragraph IV ANDA constitutes a "highly artificial" act of infringement, establishing subject matter jurisdiction for the Court to determine whether the patents identified in the Paragraph IV letter are valid and would be infringed by the sale and manufacture of the proposed generic drug product identified in the ANDA, even though the generic drug product itself has not yet been sold. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990). After receiving a Paragraph IV letter, brand manufacturers are given 45 days to bring a suit for patent infringement under 35 U.S.C. § 271 (e)(2); 21 U.S.C. § 355(j)(5)(B)(iii). The mere act of filing within 45 days prevents the FDA from approving the generic's ANDA for thirty (30) months unless the generic prevails on the merits at the District Court level before that

time. 21 U.S.C. § 355(j)(5)(B)(iii). Until a final decision is reached, the brand manufacturer enjoys unchallenged exclusivity in the marketplace. In exchange for this automatic 30-month stay, Congress also imposed the express statutory requirements that all parties "reasonably cooperate in expediting the action." 21 U.S.C. § 355(j)(5)(B)(iii); *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 403 F.Supp.2d 484, 490 (E.D. Va. 2005) ("Obviously, this process is designed to allow for the court to resolve any claim of infringement the original patent owner may have against the ANDA applicant as quickly as possible, and, indeed, the statute requires that, in these actions, 'each of the parties shall reasonably cooperate in expediting the action.'" (quoting analogous provision of 21 U.S.C. § 355(c)(3)(C))), *rev'd on other grounds*, 499 F.3d 1299 (Fed. Cir. 2007) (reversing the grant of summary judgment of infringement on the merits).

Under these statutory regulations, as the Court is well aware, the generic is entitled to expeditious judicial resolution of this matter to get its less expensive generic equivalents to market. Any delay in resolution significantly favors the brand pharmaceutical company, which gets to maintain its monopoly profits and higher prices until the patent dispute is resolved.

II. STATEMENT OF FACTS

Apotex, Inc. submitted its ANDA No. 79-013 seeking FDA approval to market and sell a generic version of Sanofi's Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product before the patents that Sanofi has listed with the FDA as covering that product expire. (Exh. B at Answer ¶ 12). The ANDA was prepared in Canada, where Apotex, Inc. is located. (Exh. B at Answer ¶ 3). Apotex, Inc. provided Sanofi with Paragraph IV notice of its ANDA No. 79-013, certifying that Sanofi's U.S. Patent Nos. 4,661,491 and 6,149,940 ("the '491 patent" and "the '940 patent" respectively) were not infringed or invalid. (Exh. B at Counterclaim Paragraphs ¶¶15, 16). After receiving Apotex's notice letters, Sanofi filed two identical lawsuits naming Apotex, Inc. and Apotex Corp. as parties. Sanofi filed the first lawsuit on December 6, 2007

(Dkt. 1) in this District ("the Delaware litigation") and the second, days later, on December 10, 2007, in the Southern District of Florida ("the Florida litigation"). *See* Exh. A, Florida Complaint. On December 28, 2007, the Apotex parties answered, counterclaimed and consented to proceed in the Southern District of Florida. *See* Exh. B, Florida Answer/Counterclaims. Since that date, the Apotex parties have answered and counterclaimed in the Delaware litigation, but preserved its position that this matter should be transferred to the Southern District of Florida and joined with the co-pending litigation. (Del. Answer ¶ 10 (Dkt. 7)). Sanofi has now answered Apotex's counterclaim in Florida. The parties also have begun discovery there, having exchanged initial disclosures, and Apotex also has served discovery requests on Sanofi in the Florida action in accordance with the Florida court's discovery schedule, which sets a discovery cut-off date of August 6, 2008 (for both fact and expert testimony) and a trial date of October 6, 2008. (Exh. C).

ARGUMENT

I. PROCEEDING IN FLORIDA WOULD EXPEDITE RESOLUTION OF THIS ACTION

As noted above, the Hatch-Waxman Act requires the parties to an ANDA action to cooperate with each other in expediting the resolution of the action. 21 U.S.C. § 355(j)(5)(B)(iii) ("In such an action, each of the parties shall reasonably cooperate in expediting the action."). Apotex now asks the Court to enforce the intent of the Hatch-Waxman Act and allow this litigation to proceed in the most expeditious fashion, which means transferring this case to Florida.

There can be no dispute that a transfer to Florida would expedite this litigation. On January 22, 2008, the Florida Court entered a revised scheduling Order setting trial for October, 2008 and a discovery cut-off of August 6, 2008 and a summary judgment deadline of August 20,

2008. Exh. C. The parties already have exchanged Rule 26(a)(1) disclosures, and Apotex already has served discovery requests. It is highly unlikely that the Delaware action will proceed towards resolution as quickly as the Florida action. Sanofi filed suit in Delaware against 13 other ANDA holders also seeking to market alfuzosin hydrochloride extended release tablets, for the alleged infringement of the '491 patent. Sanofi also sued several of these companies for infringement of the '940 patent. Although Sanofi has not yet sued Apotex for infringement of the '940 patent, Apotex has counterclaimed seeking a declaration that its ANDA product does not infringe that patent because Apotex's proposed drug product is different from what is claimed in the '940 patent. Given Sanofi's disparate treatment of Apotex's ANDA product as compared with many of the other generic competitors that it sued in Delaware on the '940 patent, it is likely that Apotex's ANDA product is substantially different (and therefore not infringing) from the other Delaware defendants, and that the Delaware litigation against Apotex – whether alone or in combination with other ANDA holders – will not be in a position where discovery would be done less than seven months from now, and trial would occur less than nine months from now.[4]

Because of these differences, there is no evidentiary overlap and nothing to be gained from consolidation on the infringement issues. Indeed, consolidation on the infringement issues likely will cause delay, as the parties and the Court sort out the issues of competitive sensitivity and confidentiality amongst the other generic defendants and their competing ANDA products. All of this delay would be avoided if the present case is transferred down to Florida.

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[4] Although Apotex's ANDA product does not infringe Sanofi's '940 patent, because Sanofi listed the '940 patent in the Orange Book it remains a cloud over Apotex's ANDA product, and is delaying Apotex's ability to get to market. *See Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006). Accordingly, Apotex has counterclaimed against Sanofi seeking patent certainty and a judicial declaration that the '940 patent also is not infringed by its ANDA product. *See Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1340 (Fed. Cir. 2007).

To be sure there may be overlap between the Delaware parties' invalidity arguments and those of Apotex. But the evidence and arguments raised also may be significantly different, as each party determines its strongest defenses. To the extent that the invalidity or other issues in the case overlap, the remaining Delaware cases will benefit from the work already done on those issues in Florida. And the rulings in Florida, while not binding, will surely be instructive and also will help to narrow if not resolve the issues remaining here to everyone's benefit.

II. THE LOCATION OF EVIDENCE, CONVENIENCE OF PARTIES AND WITNESSES, AND THE INTERESTS OF JUSTICE WEIGH IN FAVOR OF TRANSFER

The factors dictated by 28 U.S.C. § 1404 also favor transferring this case to Florida. *Jumara v. State Farm Ins. Co.* 55 F.3d 873, 879 (3d Cir. 1995) ("While there is no definitive formula or list of the factors to consider, courts have considered many variants of the private and public interests protected by the language of § 1404(a)." (internal citations omitted)). Specifically, § 1404 requires the Court to consider the location of evidence, the convenience of the parties, the convenience of the witnesses and the interests of justice. Additional public and private interest factors are outlined in the Third Circuit's decision in *Jumara v. State Farm Inc. Co.* 55 F.3d 873, 879 (3d Cir. 1995):

> The private interests have included: plaintiff's forum preference as manifested in the original choice, 1A PT.2 MOORE'S P 0.345[5], at 4363; the defendant's preference, id. § 3848, at 385; whether the claim arose elsewhere, 15 WRIGHT ET AL. § 3848; the convenience of the parties as indicated by their relative physical and financial condition, id. § 3849, at 408; the convenience of the witnesses -- but only to the extent that the witnesses may actually be unavailable for trial in one of the fora, id. § 3851, at 420-22; and the location of books and records (similarly limited to the extent that the files could not be produced in the alternative forum), id. § 3853.
>
> The public interests have included: the enforceability of the judgment, 1A PT.2 MOORE'S P 0.345[5], at 4367; practical considerations that could make the trial easy, expeditious, or inexpensive, id.; the relative administrative difficulty in the two fora resulting from court congestion, id., at 4373; 15 WRIGHT ET AL. §

> 3854; the local interest in deciding local controversies at home, 1A PT.2 MOORE'S ¶ 0.345[5], at 4374; the public policies of the fora, see 15 WRIGHT ET AL. § 3854; and the familiarity of the trial judge with the applicable state law in diversity cases. id.

Weighing these interests renders Florida the more appropriate forum. With respect to the public's interest, the public has a well-recognized interest in "receiving generic competition to brand-name drugs as soon as is possible," *Boehringer Ingelheim Corp. v. Shalala*, 993 F. Supp. 1, 3 (D.D.C. 1997), and a "delay in the marketing of [the generic] drug could easily be against the public interest in reduced prices," *Schering Corp. v. Sullivan*, 782 F. Supp. 645, 652 (D.D.C. 1992). The above-quoted sections of the Hatch-Waxman Act dealing with the parties' obligation to expedite resolution of this matter further dictate that Florida is the appropriate forum for this action. As explained above, any arguments by Sanofi concerning conservation of judicial resources through combining this action with the other cases pending here will prove illusory.

The private interests also dictate that the case should be transferred to Florida. The only connection Delaware has to this matter is the incorporation of Apotex Corp. and Sanofi-Aventis U.S. L.L.C. Neither company has active operations in Delaware. Apotex Corp.'s headquarters is located in Florida and Apotex, Inc. is located in Canada. Sanofi-Aventis U.S. is located in New Jersey and its parent, Sanofi-Aventis is located in France. Although the Defendants' state of incorporation is not irrelevant to a transfer inquiry, it certainly is not dispositive. *Mentor Graphics,* 77 F. Supp. 2d at 509 ("Although the court does not mean to suggest that a defendant's state of incorporation is irrelevant to a venue transfer inquiry, it is certainly not dispositive.").

The operative facts giving rise to this litigation are centered in Canada, France, New Jersey and Florida, *not* Delaware. 17 Moore's Federal Practice 3d, § 111.13(1)(d) at 111-71 ("If none of the operative events in the lawsuit took place in the district in which the action was

originally filed, a motion to transfer to the district in which the events occurred is likely to succeed...."). None of the alleged infringing activities took place in Delaware. (McIntire Decl. at ¶ 6-8). The filing of the ANDA with Paragraph IV certification was the purported act of infringement prompting this litigation and was initiated from Canada. (McIntire Decl. at ¶ 5-7; Tao Decl. at ¶ 6-9). None of the documents relevant to this litigation are in Delaware. (McIntire Decl. at ¶ 7; Tao Decl. at ¶ 9). The ANDA filing, Paragraph IV Certification, and further correspondence with the FDA are the operative facts and documents relevant to this litigation, all of which originated from or are located in Canada or Florida.

The convenience of the witnesses also favors transfer to Florida. All persons knowledgeable about the contents of Apotex's ANDA, and therefore potential witnesses, are located in Florida or Canada. Accordingly, Florida is a more convenient and logical forum for this litigation.

On January 8, 2008, Sanofi filed a motion to transfer the Florida action in favor of this litigation, explaining that it filed the Florida action as a protective measure because it feared the Delaware action would be dismissed for lack of personal jurisdiction. Far from being a persuasive reason to continue this litigation here, Sanofi's professed reason for suing in Florida is indicative that Florida "is clearly the better forum, as all parties agree that both jurisdiction and venue lie here." *Aventis,* 403 F.Supp.2d at 490; *see also Bristol-Myers Squibb Co. v . Andrx Pharms., LLC*, No. 03 Civ. 2503 (SHS), 2003 WL 22888804, at *5 (S.D.N.Y. Dec. 5, 2003) (rejecting argument that second-filed lawsuit in the Southern District of Florida should not proceed because patentee only filed there out of fear that the situs of the first filed action would not have jurisdiction over one of the parties). As the *Aventis* court explained neither the law nor logic support Sanofi's position:

> While Plaintiffs strongly urge Defendants' letter necessitated a "protective suit," however, they do not explain why or if the statutory framework requires such a "protective measure." **They point to no case or regulation indicating that "protective actions" are necessary or encouraged in ANDA cases.** They **do not maintain that "protective actions" "expedite the action" as the statute commands. See *21 U.S.C. § 355(c)(3)(C)*.** They provide nothing to convince this Court they could not pursue this action in solely in Maryland instead of also filing an identical action in this District. According to Plaintiffs, "the basis for personal jurisdiction over defendant Lupin India in Maryland is particularly strong," yet a "protective suit" is necessary in the event the Maryland court determines it lacks jurisdiction over Lupin Ltd., the India company. Pl.'s Mot. for Stay at 9. This Court cannot accept such a contradictory argument. **If the Maryland forum is in any way questionable in order to necessitate a "protective filing" as Plaintiffs maintain, then this Court is clearly the better forum, as all of the parties agree that both jurisdiction and venue lie here.** Plaintiffs have therefore failed to justify the need for a stay by "clear and convincing circumstances," as required by *Williford, 715 F.2d at 127*.

Aventis, 403 F. Supp. 2d at 490. (emphasis added).

Similarly, in *Bristol-Myers*, the court rejected the protective filing argument, placing particular reliance on the fact that the defendant company was located in Florida and that the "locus of operative facts" was centered there. *Bristol-Myers*, 2003 WL 22888804 at *5. Here, regardless of whether Sanofi's lawsuit in Florida was protective, Florida is the more logical and convenient forum, where the situs of many of the alleged acts of infringement took place, and where the Apotex Corp. documents and witnesses are located, and where a trial date has already been set for October of this year. Accordingly, Florida is where this case should be litigated.

III. THE FIRST FILED RULE DOES NOT APPLY WHERE A PLAINTIFF FILES BOTH SUITS; HERE, FLORIDA IS THE MORE CONVENIENT FORUM

To the extent that Sanofi seeks to rely on this lawsuit having been filed a few days before the Florida case as a basis for this Court retaining this litigation, that reliance is misplaced. The first-filed rule does not apply when a plaintiff chooses to file two identical lawsuits against the **same** party in two different venues. *Aventis*, 403 F. Supp.2d at 489 (E.D. Va. 2005) (explaining that the first-filed rule does not apply where the "Plaintiffs filed the same case against the same

Defendants in two different courts."); *Employers Reins. Corp. v. MSK Ins., Ltd.*, No. Civ. 01-2608-CM, 2003 WL 21143105, at *6 (D. Kan. Mar. 31, 2003) (declining to apply first-to-file rule, noting rule applies to "*party* who files first"); *see also Adams Resp. Therap. v. Mutual Pharm. Holdings*, No. 2:06-CV-04700-HAA-ES (D.N.J.) Dkt. No. 14, Nov. 16, 2006 Order at 2) (Exhibit D). Rather, it most often applies to situations where two opposing parties race to different courthouses to file suits against each other, a situation not present here. *See, e.g., Serco Serv. Co. L.P., v. Kelley Co., Inc.*, 51 F.3d 1037, 1039 (Fed. Cir. 1995); *Aventis,* 403 F. Supp. 2d at 489-90 (E.D. Va. 2005).

In any event, the first filed rule is not absolute, and is subsidiary to the balancing of convenience and other interests. *Id.* ("Thus, 'the trial court's discretion tempers the preference for the first-filed suit, when such preference should yield to the forum in which all interests are best served.'" (quoting *Genentech, Inc. v. Eli Lilly & Co.*, 998 F.2d 931, 938 (Fed. Cir. 1993)). For example, in *Aventis*, in rejecting the plaintiffs' first filed argument, the court explained that "its primary concern is to 'expedite the action' as directed by 21 U.S.C. § 355(c)(3)(C)." *Aventis*, 403 F. Supp. 2d at 490. There, the appropriate venue was determined to be the location (Virginia) where the person who was designated to accept service of process in the Paragraph IV certification letter was located. *Id.* at 488. Similarly here, Apotex, Inc.'s paragraph IV letters designated Tammy McIntire, Apotex Corp., 2400 N. Commerce Parkway, Suite 400, **Weston, Florida** 33326 as the person who would accept service on its behalf. (Tao Decl. ¶9).

Adams similarly holds that the first-filed rule has no place in a situation such as this, where the ANDA filer was sued in two different jurisdictions by the same patentee. There, the patentee (like Sanofi here), filed identical patent infringement actions against the ANDA-filer in both New Jersey and Pennsylvania. The ANDA-filer immediately answered and counterclaimed

in Pennsylvania and consented to proceed there. The patentee objected. Invoking the first-filed rule, the patentee moved to stay the Pennsylvania action that it voluntarily filed and asked the New Jersey Court to enjoin the Pennsylvania court from proceeding. The patentee's arguments were rejected and the second-filed Pennsylvania action was permitted to continue.

> The "first-filed rule' is intended to prevent duplicative litigation, but I do not believe the rule was intended to provide a single plaintiff the opportunity to institute identical suits in various jurisdictions and then put all but the first one on the back burner until such time as the plaintiff deems convenient.

Id.

The court in the second filed Pennsylvania action similarly rejected the patentee's arguments seeking to stay or transfer the action, explaining:

> . . . I believe granting a stay here would encourage judge-shopping. I do not believe the "first-filed" rule – on which the Plaintiff almost exclusively relies – applies in the unique circumstances presented here . . . . I believe it would be inappropriate to allow a plaintiff to file identical actions in different courts and then pick the court in which it wishes to proceed while the other action is stayed pending the result in the first-filed action. Plaintiff has chosen to sue here; it can not credibly complain that proceeding with this suit is prejudicial.

Adams Resp. Therap. v. Mutual Pharm. Holdings, No. 2:06-cv-04418-PD (E.D. Pa.), Dkt. No. 31, Nov. 2, 2006 (Order at 2) (Exhibit E).

Even if the first-filed rule had some application here, the fact remains that the Delaware and Florida litigations were filed within a few days of each other, so there is no prejudice to Sanofi with proceeding with that action over the Delaware case. By filing the second lawsuit in Southern District of Florida, and availing themselves of that forum, Plaintiffs accepted the possibility of having to litigate this case in Florida. No claimed hardship, as a result of dismissal in favor of the Florida litigation, should be recognized by this Court.

CONCLUSION

For the foregoing reasons, the Delaware litigation should be transferred in favor of proceeding with the Florida litigation, or in the alternative stayed until final resolution of the Florida litigation.

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Dated: January 24, 2008
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, Richard L. Horwitz, hereby certify that on January 24, 2008, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

I hereby certify that on January 24, 2008, I have Electronically Mailed the document to the following person(s)

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EXHIBIT A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

Case No. 07-61800

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants. /

CIV-MORENO

MAGISTRATE JUDGE
SIMONTON

COMPLAINT

Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), for their Complaint against Defendants Apotex Inc. and Apotex Corp., hereby allege as follows:

Parties

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Upon information and belief, Defendant Apotex Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc., which is in turn a wholly-owned

subsidiary of Apotex Holdings Inc. Upon information and belief, Defendant Apotex Inc. manufactures numerous generic drugs for sale and use throughout the United States, including in this judicial district.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

Nature of the Action

5. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

Jurisdiction and Venue

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to a company, Plaintiff sanofi-aventis U.S., which manufactures numerous drugs for sale and use throughout the United States, including in this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

8. This Court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia*: (1) its presence in Florida through its sister corporation and agent Apotex Corp.; and (2) its systematic and continuous contacts with Florida, including through its sister corporation and agent Apotex Corp.

9. This Court has personal jurisdiction over Apotex Corp. by virtue of the fact that, *inter alia*, Apotex Inc. is a Florida corporation.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The '491 Patent

11. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral® in the United States. The '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

Acts Giving Rise to this Action

Infringement of the '491 Patent by Defendants

12. Upon information and belief, Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") 79-013 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-013 specifically seeks FDA approval to market a

proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

13. Apotex Inc. alleged in ANDA 79-013 under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of the § 505(j)(2)(A)(vii)(IV) allegation related to the '491 patent in ANDA 79-013 on or about October 25, 2007.

14. Apotex Inc.'s submission of ANDA 79-013 to the FDA, including the § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Apotex Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

15. Apotex Corp. is jointly and severally liable for Apotex Inc.'s infringement of the '491 patent. Upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced Apotex Inc.'s submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA.

16. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, Apotex Corp.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

17. This is an exceptional case under 35 U.S.C. § 285 because Defendants were aware of the existence of the '491 patent at the time of the submission of ANDA 79-013 and their § 505(j)(2)(A)(vii)(IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

18. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

19. Plaintiffs have sought to enjoin Defendant Apotex Inc.'s and Defendant Apotex Corp.'s infringing activities in an action filed by Plaintiffs in the District of Delaware on December 7, 2007, Civil Action No. 07-792 and will seek to have that action coordinated or consolidated with an action brought to enjoin acts of infringement of the '491 patent by numerous defendants filed by Plaintiffs in the District of Delaware on September 21, 2007, Civil Action No. 07-572 GMS (MPT). Defendant Apotex Inc. and Defendant Apotex Corp. are properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted by all of Plaintiffs' claims for infringement of the '491 patent being addressed in the District of Delaware. Upon information and belief, Plaintiffs understand that Defendants may nevertheless contest jurisdiction in that venue. Given the possible consequences if Defendants succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendants are unsuccessful in any such challenge, Plaintiffs will dismiss this action.

Prayer for Relief

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Defendants have infringed the '491 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Apotex Inc.'s ANDA identified in this Complaint shall not be earlier than the expiration date of the '491 patent, including any extensions;

C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently

enjoined from commercially manufacturing, using, offering for sale, or selling the proposed generic version of sanofi-aventis' Uroxatral® brand product identified in this Complaint, and any other product that infringes or induces or contributes to the infringement of the '491 patent, prior to the expiration of the '491 patent, including any extensions;

D. That this case is exceptional under 35 U.S.C. § 285;

E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

Dated this 10th day of December, 2007.
Miami, Florida

Respectfully submitted,

Alfred J. Saikali (Fla. Bar No. 178195)
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Miami Center, Suite 2400
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Telephone: (305)358-5171
Facsimile: (305)358-7470
Attorney for Plaintiffs sanofi-aventis and sanofi-aventis U.S. LLC

EXHIBIT A

United States Patent [19]

Regnier

[11] **Patent Number: 4,661,491**

[45] **Date of Patent: Apr. 28, 1987**

[54] **ALFUZOSINE COMPOSITIONS AND USE**

[75] Inventor: **François Regnier**, Nancy, France

[73] Assignee: **Synthelabo**, Paris, France

[21] Appl. No.: **867,031**

[22] Filed: **May 27, 1986**

[30] **Foreign Application Priority Data**

May 28, 1985 [FR] France 85 07950

[51] **Int. Cl.**[4] **A61K 31/505**
[52] **U.S. Cl.** **514/260**
[58] **Field of Search** 514/260

[56] **References Cited**

U.S. PATENT DOCUMENTS

4,315,007 2/1982 Manoury 514/259

Primary Examiner—Allen J. Robinson
Attorney, Agent, or Firm—Wegner & Bretschneider

[57] **ABSTRACT**

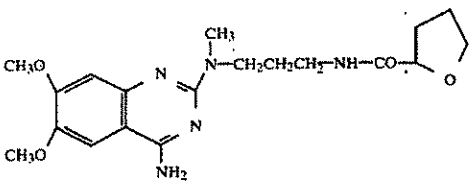
A method for treating humans or non-human animals for dysuria comprising administering an effective non-toxic amount of alfuzosine or a pharmaceutically acceptable salt thereof to a human or non-human animal suffering dysuria.

5 Claims, No Drawings

ALFUZOSINE COMPOSITIONS AND USE

The present invention relates to pharmaceutical compositions containing alfuzosine and the use of alfuzosine in the treatment of dysuria.

Alfuzosine, the compound of formula



is known for its antihypertensive activity. It is an antagonist of vascular α_1-adrenergic receptors which possesses direct muscle-relaxant properties.

In many patients manifesting dysuria, an exceptionally high cervico-urethral pressure is observed, which is related to a relative hyperactivity of the α-adrenergic receptors.

It has now been found that alfuzosine has activitity in altering the phenylephrine-induced contractions on preparations of smooth muscle originating from the base of the bladder (trigone muscle) and the urethra of rabbits and that alfuzosine can be used for the treatment of conditions of the lower urinary apparatus, in which hyperactivity of the alpha-adrenergic receptors of the vesicosphincter system disturbs the continence/micturition cycle.

Accordingly the present invention provides a method for treating dysuria in humans or non-human animals comprising administering a therapeutic amount of alfuzosine or a pharmaceutically acceptable salt thereof to a human or animal suffering dysuria.

Patients who may be treated are, for example, men and women who have bladder neck disease, or men who have benign hypertrophy of the prostrate with dysuria of alpha-adrenergic origin.

Other patients who may be treated include those suffering from neurological disorders such as paraplegia or multiple sclerosis, for whom the disturbance of micturition also responds to alfuzosine.

The daily dosage can range from 0.5 to 10 mg for adult humans.

The present invention also provides a pharamceutical composition for treating dysuria comprising an effective amount of alfuzosine or a pharmaceutically acceptable salt thereof and a pharmaceutical diluent or carrier therefor.

The pharmaceutical compositions of the invention containing alfuzosine or a pharmaceutically acceptable salt thereof in combination with any suitable excipient can be administered orally, parenterally or transdermally. They are presented in any suitable form such as gelatine capsules, tablets, solutions, and the like. The pharmaceutical compositions can also be presented in the form of delayed-release tablets or gelatine capsules.

The pharmaceutically acceptable salts include acid addition salts of a pharamceutically acceptable organic or inorganic acid such as mineral acids and mono-, di- or tri- carboxylic acids, especially the hydrochloride salt.

The invention will now be illustrated by the following Pharmacological Data and Formulation Examples.

PHARMACOLOGICAL DATA

Male rabbits (CEGAN) weighing 3 to 4 kg are sacrificed by exsanguination and cervical dislocation.

The bladder and urethra are rapidly removed and placed in lukewarm Krebs solution containing bicarbonate.

The composition of this Krebs medium is as follows, in mM: NaCl 114; KCl 4.7; $CaCl_2$ 2.5; KH_2PO_4 1.2; $MgSO_4$ 1.2; $NaHCO_3$ 25.0; glucose 11.7; ascorbic acid 1.1. Propranolol (1.0 μM) is added into the Krebs medium to block the β-adrenergic receptors.

The bladder is opened transversely and the "trigone" region of the muscle, located on the dorsal surface of the bladder and between the two ureters, is dissected out.

A 5 mm ring of urethra, from the region situated between the base of the bladder and the prostate, is also prepared.

The portions of trigone muscle and urethra are washed under a tension of 1 g in Krebs medium.

The contraction-response curve to cumulated concentrations of phenylephrine is determined.

Additions of the agonist are performed every 5 min. The tissues are washed until the original tension is reestablished, and are then incubated for 30 min with alfuzosine. A second response curve to phenylephrine is determined in the presence of alfuzosine.

The response curves to concentrations of phenylephrine in the presence or absence of alfuzosine are expressed as a percentage of the maximum response obtained relative to the control curve.

The power of alfuzosine is calculated in the form of pA_2 by Schild's method, where pA_2=negative logarithm of the molar concentration of alfuzosine which causes a rightward shift of the response curve to the agonist.

Alfuzosine (at a dose of 3.0 μM) causes a significant rightward parallel shift of the response curve to phenylephrine both in the trigone muscle and in the urethra. Alfuzosine causes a 20 to 30% reduction in the maximum contractile effects of phenylephrine.

By Schild analysis, the pA_2 can be determined, this being 7.05–0.17.

By means of clinical studies, it has also been possible to show the efficacy of alfuzosine in patients suffering from dysuria of neurological origin with urethral hypertonia.

5 mg of alfuzosine are injected intravenously continuously for a period of 20 min. Sphincterometric measurements were made using an electronic micro-sensor, before and after the injection of the drug, at the bladder neck and at the striated sphincter of the posterior urethra.

The results of these measurements enabled a 44% pressure decrease ($p<0.001$) to be noted at the bladder neck, and a 39% decrease ($p<0.001$) at the striated sphincter.

A clinical study was also performed in paraplegics.

The paraplegic, or spinal man, gives rise to an experimental model of the peripheral receptors, since he embodies a disconnection from the influence of the higher, diencephalic and cortical nerve centres.

Given the localization of the alpha-adrenergic receptors in the posterior urethra and the vesico-urethral segment or neck, alpha-adrenergic hypertonia is the

source of dysuria and disturbances of micturition. The opening of the neck and the fall in the pressure gradient in the posterior urethra are the two conditions required for the production of effective micturition.

Alfuzosine was administered intravenously, and then orally if the first test is positive. 5 mg of alfuzosine are injected intravenously in the course of 20 min.

After injection of alfuzosine, the intra-urethral pressures decrease significantly. The test is considered to be positive if an initiation of micturition, that is to say, necessarily, opening of the neck, takes place.

For patients for whom the test is positive, the administration of alfuzosine was then performed orally at the rate of 9 mg/24 h/28 d.

In most cases, the treatment per os enabled micturition to be rendered easier to initiate.

FORMULATION EXAMPLES

Examples of pharmaceutical formulations are given below:

	mg
Tablet:	
Alfuzosine (as the hydrochloride salt)	5
Microcrystalline cellulose	36
Lactose	122
Sodium carboxymethylamide	7
Polyvidone excipient	9
Magnesium stearate	1
	180
Coating env.	8
Injectable Solution	
Alfuzosine (as the hydrochloride salt)	1
Sodium chloride	44.9
Water for injection qs	5 ml

I claim:

1. A method for treating humans or non-human animals for dysuria comprising administering an effective dysuria controlling, non-toxic amount of alfuzosine or a pharmaceutically acceptable salt thereof to a human or non-human animal suffering dysuria.

2. A method according to claim 1 comprising administering alfuzosine hydrochloride.

3. A method according to claim 1 comprising administering from 0.5 to 10 mg of alfuzosine or the corresponding amount of a pharmaceutically acceptable salt thereof.

4. A method according to claim 1 for treating dysuria in patients having bladder neck disease or a neurological disorder.

5. A method according to claim 1 for treating dysuria in male patients having benign hypertrophy of the prostrate of alpha-adrenergic origin.

* * * * *

JS 44 (Rev. 11/05)

CIVIL COVER SHEET

07-61800

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.) **NOTICE: Attorneys MUST Indicate All Re-filed Cases Below.**

I. (a) PLAINTIFFS
sanofi-aventi and
sanofi-aventis U.S. LLC

(b) County of Residence of First Listed Plaintiff France
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

DEFENDANTS
Apotex Inc. and
Apotex Corp.

County of Residence of First Listed Defendant Broward
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT LAND INVOLVED.

Attorneys (If Known) **CIV-MORENO**

(d) Check County Where Action Arose: ☐ MIAMI- DADE ☐ MONROE ☒ BROWARD ☐ PALM BEACH ☐ MARTIN ☐ ST. LUCIE ☐ INDIAN RIVER ☐ OKEECHOBEE ☐ HIGHLANDS

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

☐ 1 U.S. Government Plaintiff
☒ 3 Federal Question (U.S. Government Not a Party)
☐ 2 U.S. Government Defendant
☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

FIL- 07 CV 61800 FAM/Simonton

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
[illegible]	☐ 3	☐ 3	[illegible]	☐ 6	☐ 6

MAGISTRATE JUDGE SIMONTON

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury - Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881	PROPERTY RIGHTS	☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	☐ 820 Copyrights	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☒ 830 Patent	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 840 Trademark	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health		☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other		☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability	LABOR	SOCIAL SECURITY	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury		☐ 710 Fair Labor Standards Act	☐ 861 HIA (1395ff)	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability			☐ 720 Labor/Mgmt. Relations	☐ 862 Black Lung (923)	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise			☐ 730 Labor/Mgmt.Reporting & Disclosure Act	☐ 863 DIWC/DIWW (405(g))	☐ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS	☐ 740 Railway Labor Act	☐ 864 SSID Title XVI	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence	☐ 790 Other Labor Litigation	☐ 865 RSI (405(g))	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:	☐ 791 Empl. Ret. Inc. Security Act	FEDERAL TAX SUITS	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General		☐ 870 Taxes (U.S. Plaintiff or Defendant)	☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty		☐ 871 IRS—Third Party 26 USC 7609	☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other			☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights			☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition			

FILED by INTAKE D.C.
DEC 10 2007
CLARENCE MADDOX
CLERK U.S. DIST. CT.
S.D. OF FLA.

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Re-filed- (see VI below) ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. RELATED/RE-FILED CASE(S). (See instructions second page):

a) Re-filed Case ☐ YES ☐ NO b) Related Cases ☒ YES ☐ NO

JUDGE Sleet Manning

DOCKET NUMBER 1:07-cv-00572-GMS (D. Del.) 1:07-cv-00574-GMS (D. Del.) 1:07-cv-00792 (D. Del.) 1:07-cv-5807 (N.D. Ill.)

VII. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing and Write a Brief Statement of Cause **(Do not cite jurisdictional statutes unless diversity):**
35 U.S.C. Section 271
Patent Infringement

LENGTH OF TRIAL via _____ days estimated (for both sides to try entire case)

VIII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☐ Yes ☒ No

ABOVE INFORMATION IS TRUE & CORRECT TO THE BEST OF MY KNOWLEDGE

SIGNATURE OF ATTORNEY OF RECORD

DATE Dec. 10, 2007

FOR OFFICE USE ONLY

AMOUNT 350 RECEIPT # 97192 IFP

EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
Case No. 07-61800-CIV-MORENO/SIMONTON

SANOFI-AVENTIS and
SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and
APOTEX CORP.,

Defendants.
_____/

ANSWER OF APOTEX INC. AND APOTEX CORP. TO COMPLAINT, AFFIRMATIVE DEFENSES AND AMENDED COUNTERCLAIMS[1]

Defendants, Apotex Inc. and Apotex Corp., Answer the Complaint of Plaintiffs, Sanofi-Aventis and Sanofi-Aventis U.S. LLC (collectively "Sanofi") as follows:

Parties

1. Plaintiff sanofi-aventis is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

ANSWER: Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 1 of the Complaint, and on that basis deny such averments.

2. Plaintiff sanofi-aventis U.S. is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

[1] This pleading is identical to the pleading filed December 28, 2007, except that certain inadvertent typographical errors in paragraphs 9, 11, 15 and 16 of the Counterclaims have been corrected.

ANSWER: Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the averments in Paragraph 2 of the Complaint, and on that basis deny such averments.

3. Upon information and belief, Defendant Apotex Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Upon information and belief, Apotex Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings Inc., which is in turn a wholly-owned subsidiary of Apotex Holdings Inc. Upon information and belief, Defendant Apotex Inc. manufacturers numerous generic drugs for sale and use throughout the United States, including in this judicial district.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. is a company organized and existing under the laws of Canada with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9; that Apotex, Inc. is a wholly owned subsidiary of Apotex Pharmaceutical Holdings, Inc. and that Apotex, Inc. manufacturers numerous drugs that are sold and used in this judicial district. Apotex, Inc. and Apotex Corp. deny that Apotex Pharmaceutical Holdings, Inc. is a wholly-owned subsidiary of Apotex Holdings, Inc. Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to the truth or falsity of the remaining averments in Paragraph 3 with respect to whether its products are sold and used "throughout the United States", and on that basis deny such averments.

4. Upon information and belief, Defendant Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326. Upon information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex Corp. is a corporation organized and existing under the laws of Delaware with a place of business at 2400 North Commerce Parkway, Weston, Florida 33326, but deny that Apotex Corp. is a wholly-owned subsidiary of Apotex Holdings Inc.

Nature of the Action

5. This is a civil action for the infringement of United States Patent No. 4,661,491 ("the '491 patent") (Exhibit A). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

ANSWER: Apotex, Inc. and Apotex Corp. admit that Plaintiffs' Complaint purports to bring this action for the alleged infringement of United States Patent No. 4,661,491 ("the '491 patent") and that a copy of the '491 patent appears to be attached to the Complaint as Exhibit A. Apotex, Inc. and Apotex Corp. also admits that Plaintiffs purport to bring this action based on the Patent Laws of the United States, 35 U.S.C. §1 et seq.

Jurisdiction and Venue

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Apotex, Inc. and Apotex Corp. admit that this Court has subject matter jurisdiction over the subject matter of this action.

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortuous action of patent infringement that has led to foreseeable harm and injury to a company, Plaintiff Sanofi-Aventis U.S., which manufacturers numerous drugs for sale and use throughout the United States, including in this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

ANSWER: Apotex Corp. admits that this Court has personal jurisdiction over it in this District for the purposes of this action. For purposes of this action, Apotex, Inc. does not contest the Court's personal jurisdiction over it. Apotex, Inc. and Apotex Corp. deny the averments against them to the extent they assert Apotex, Inc. and Apotex Corp. committed or aided, abetted, contributed to and/or participated in the commission of the referenced acts of patent

infringement or that Plaintiff Sanofi-Aventis U.S. has been injured or otherwise harmed through any alleged tortious acts of Defendants. As to the remaining averments, Apotex, Inc. and Apotex Corp. lack knowledge or information sufficient to form a belief as to their truth or falsity and on that basis deny such averments.

8. This Court has personal jurisdiction over Defendant Apotex Inc. by virtue of, *inter alia*: (1) its presence in Florida through its sister corporation and agent Apotex Corp.; and (2) its systematic and continuous contacts with Florida, including through its sister corporation and agent Apotex Corp.

ANSWER: For purposes of this action, Apotex, Inc. does not contest the Court's jurisdiction over it, but denies the alleged basis for personal jurisdiction asserted in this paragraph, including that Apotex Corp. is Apotex, Inc.'s "sister corporation and agent."

9. This Court has personal jurisdiction over Apotex Corp. By virtue of the fact that, *inter alia*, Apotex Inc. is a Florida corporation.

ANSWER: Apotex Corp. does not contest the Court's jurisdiction over it in this action, but denies that Apotex Inc. is a Florida corporation. Apotex Corp. does have its principal place of business in Florida at 2400 North Commerce Parkway, Weston, Florida 33326.

10. Venue is proper in this judicial district as to each defendant pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Apotex, Inc. and Apotex Corp. admit that venue is proper in this judicial district.

The '491 Patent

11. On April 28, 1987, the '491 patent, titled "Alfuzosine Compositions and Use," was duly and legally issued by the United States Patent and Trademark Office ("PTO"). Plaintiff sanofi-aventis is the current assignee of the '491 patent. Plaintiff sanofi-aventis U.S. holds New Drug Application ("NDA") No. 21-287 on Uroxatral® brand alfuzosin hydrochloride extended release tablets, and is the exclusive distributor of Uroxatral® in the United States. The '491 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral®.

ANSWER: Apotex, Inc. and Apotex Corp. admit that the '491 patent issued on April 28, 1987, but deny that this patent was duly and legally issued. Apotex, Inc. and Apotex Corp. admit that this patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Uroxatral® and that Sanofi-Aventis U.S. is listed as the Applicant for NDA No. 21-287. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the remaining averments of Paragraph 11 of the Complaint, and on that basis deny such averments.

Acts Giving Rise to this Action
Infringement of the '491 Patent by Defendants

12. Upon information and belief, Apotex Inc. submitted Abbreviated New Drug Application ("ANDA") 79-013 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). That ANDA seeks FDA approval for the commercial manufacture, use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet. ANDA 79-013 specifically seeks FDA approval to market a proposed generic version of sanofi-aventis' Uroxatral® brand alfuzosin hydrochloride 10 mg tablet product prior to the expiration of the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. filed its ANDA No. 79-013 with the FDA seeking approval for generic Alfuzosin Hydrochloride Extended-release Tablets in 10mg strength. Defendants admit that Apotex, Inc. seeks FDA approval to market the proposed product identified in its ANDA prior to the expiration of the '491 patent. The remaining averments of this paragraph are denied.

13. Apotex Inc. alleged in ANDA 79-013 under § 505(j) (2) (A) (vii) (IV) of the Federal Food, Drug and Cosmetic Act that the claims of the '491 patent are invalid. Plaintiffs received written notification of the § 505(j) (2) (A) (vii) (IV) allegation related to the '491 patent in ANDA 79-013 on or about October 25, 2007.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Apotex, Inc. provided Plaintiffs with notice of its ANDA No. 79-013, that such notice satisfied all statutory and regulatory

requirements and that Plaintiffs received notice on or about October 25, 2007. The remaining averments of this paragraph are denied.

14. Apotex Inc.'s submission of ANDA 79-013 to the FDA, including the § 505(j) (2) (A) (vii) (IV) allegations, constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Apotex Inc.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 14 of the Complaint.

15. Apotex Corp. is jointly and severally liable for Apotex Inc.'s infringement of the '491 patent. Upon information and belief, Apotex Corp. participated in, contributed to, aided, abetted and/or induced Apotex Inc.'s submission of ANDA 79-013 and its § 505(j)(2)(A)(vii)(IV) allegation to the FDA.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 15 of the Complaint.

16. Apotex Corp.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA 79-013 and its § 505(j) (2) (A) (vii) (IV) allegations to the FDA constitutes infringement of the '491 patent under 35 U.S.C. § 271(e) (2) (A). Moreover, Apotex Corp.'s commercial use, offer for sale or sale of its proposed generic version of sanofi-aventis' Uroxatral® brand product would infringe the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 16 of the Complaint.

17. This is an exceptional case under 35 U.S.C. § 285 because Defendants were aware of the existence of the '491 patent at the time of the submission of ANDA 79-013 and their § 505(j) (2) (A) (vii) (IV) allegations to the FDA and that filing constituted infringement of the '491 patent.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 17 of the Complaint. Further, this allegation has no basis in fact or law and unless it is withdrawn, Defendants will seek sanctions under Rule 11 of the Federal Rules of Civil Procedure.

18. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this court. Plaintiffs do not have an adequate remedy at law.

ANSWER: Apotex, Inc. and Apotex Corp. deny the averments in Paragraph 18 of the Complaint.

19. Plaintiffs have sought to enjoin Defendant Apotex Inc.'s and Defendant Apotex Corp.'s infringing activities in an action filed by Plaintiffs in the District of Delaware on December 7, 2007 Civil action No. 07-792 and will seek to have that action coordinated or consolidated with an action brought to enjoin acts of infringement of the '491 patent by numerous defendants filed by Plaintiffs in the District of Delaware on September 21, 2007, Civil Action No. 07-572 GMS (MPT). Defendant Apotex Inc. and Defendant Apotex Corp. are properly subject to personal jurisdiction in the District of Delaware and judicial economy would be promoted by all of Plaintiffs' claims for infringement of the '491 patent being addressed in the District of Delaware. Upon information and belief, Plaintiffs understand that Defendants may nevertheless contest jurisdiction in that venue. Given the possible consequences if Defendants succeeded with such unjustified action, Plaintiffs had no choice but to file this Complaint. In the event that Defendants are unsuccessful in any such challenge, Plaintiffs will dismiss this action.

ANSWER: Apotex, Inc. and Apotex Corp. admit that Plaintiffs filed an action against them in the District of Delaware. Apotex, Inc. and Apotex Corp. are without sufficient knowledge or information to form a belief as to the truth or falsity of the averments concerning Plaintiffs' intentions, knowledge or beliefs, and on that basis deny such averments. Apotex, Inc. and Apotex Corp. deny that Apotex, Inc. is subject to personal jurisdiction in the Delaware action and deny that judicial economy would be promoted by proceeding with the Delaware action as opposed to this action.

GENERAL DENIAL

Any allegation in Plaintiffs' Complaint not expressly admitted by Defendants are hereby denied. Having answered Plaintiffs' Complaint, Defendants deny that Plaintiffs are entitled to the relief requested in Plaintiffs' Prayer for Relief or any relief whatsoever.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer to the Complaint, and without admitting any allegations of the Complaint not otherwise admitted, Defendants assert the following affirmative defenses to the Complaint:

FIRST AFFIRMATIVE DEFENSE

The manufacture, use, sale, offer for sale or importation into the United States of the product that is the subject of Apotex Inc.'s ANDA No. 79-013 has not infringed, does not infringe, and would not, if marketed, infringe one or more of the claims of the '491 patent, either literally or under the doctrine of equivalents.

SECOND AFFIRMATIVE DEFENSE

The claims of the '491 patent are invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD AFFIRMATIVE DEFENSE

Plaintiffs have failed to state a claim on which relief can be granted. Defendants reserve their right to assert any and all additional defenses and counterclaims that discovery may reveal.

AMENDED COUNTERCLAIMS

Apotex Inc. and Apotex Corp., (collectively "counterplaintiffs") for their Counterclaims against Sanofi-Aventis ("Sanofi-Aventis") and Sanofi-Aventis U.S. LLC ("Sanofi-Aventis U.S.") (the counter-defendants will be referred to herein collectively as "Sanofi"), allege as follows:

The Parties

1. Apotex Inc. is a Canadian corporation having a place of business at 150 Signet Drive, Ontario, Canada M9L 1 T9.

2. Apotex Corp. is a Delaware corporation having a place of business at 2400 North Commerce Parkway, Suite 400, Weston Florida 33326.

3. Sanofi-Aventis U.S. has alleged that it is a limited liability company organized and existing under the laws of Delaware with its North American headquarters located at 55 Corporate Drive, Bridgewater, New Jersey 08807.

4. Sanofi-Aventis has alleged that it is a corporation organized and existing under the laws of France, having its principal place of business at 174 avenue de France, Paris, France 75013.

Jurisdiction and Venue

5. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355) (hereinafter "Hatch-Waxman Amendments"), and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub.L. No. 108-173, 117 Stat. 2066 (2003) (hereinafter "MMA").

6. The Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338 (a).

7. The Court has personal jurisdiction over Sanofi because Sanofi has availed themselves to the rights and privileges of this forum by suing counterplaintiffs in this District

and because Apotex Corp. conducts substantial business in and has regular systematic contacts with this District.

8. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400 (b).

Patents-in-Suit

9. On or about April 28, 1987, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,661,491 ("the '491 patent"), entitled "ALFUZOSINE COMPOSITIONS AND USE" to Francois Regnier.

10. Sanofi-Aventis purports to own and to have the right to enforce the '491 patent.

11. On or about November 21, 2000, the PTO issued U.S. Patent No. 6,149,940 ("the '940 patent") entitled "TABLET WITH CONTROLLED RELEASE OF ALFUZOSINE CHLORHYDRATE" to Lauretta Maggi, Ubaldo Conte, Busto Arisizio, Pascal Grenier, Guy Vergnault, Alain Dufour, Francois Xavier Jarreau and Clemence Rauch-Desanti.

12. Sanofi-Aventis purports to own an interest in'940 patent and on information and belief has an exclusive license and the right to unilaterally bring and proceed with lawsuits to enforce the '940 patent in its own name.

13. Sanofi-Aventis U.S. is identified as the owner of New Drug Application No. 21-287 on Uroxatral brand alfuzosin hydrochloride extended release tablets. The '491 patent and the '940 patent are listed in the Orange Book for Uroxatral.

14. Sanofi has attempted to enforce the '940 patent against multiple other ANDA filers seeking FDA approval for alfuzosin hydrochloride extended release tablets.

15. Apotex has submitted an abbreviated new drug application (ANDA) No. 79-013 to the FDA. Apotex Inc.'s ANDA seeks FDA approval for the commercial use, offer for sale and sale of generic extended release tablets containing 10 mg of alfuzosin hydrochloride per tablet.

16. Pursuant to 21 U.S.C. § 355(j) (2) (B) (ii) and 21 C.F.R. § 314.95, Apotex, Inc. has certified to Sanofi that the '491 patent and the '940 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use of sale of the new drug for which ANDA 79-013 is submitted.

17. On or about August 14, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '940 patent.

18. On or about October 15, 2007, Apotex, Inc. served Sanofi with a Paragraph IV certification letter informing Sanofi of its ANDA to obtain approval to engage in the commercial manufacture, use or sale of its alfuzosin hydrochloride extended release tablets before the expiration of the '491 patent.

19. On or about December 10, 2007, Sanofi sued Apotex Inc and Apotex Corp in this District alleging infringement of the '491 patent under 35 U.S.C. § 271 (e)(2)(A).

20. Counterplaintiffs have a reasonable apprehension of being sued by Sanofi for alleged infringement of the '940 patent because, *inter alia*, Apotex, Inc. has served Sanofi with its Paragraph IV certification letter asserting that the'940 patent was not infringed, Sanofi has sued more than ten other ANDA holders seeking to market alfuzosin hydrochloride extended release tablets for alleged infringement of the '940 patent, and Sanofi already has sued counterplaintiffs for infringement of the '491 patent in this court.

21. As a result of Sanofi's actions in listing of the '491 and '940 patents in the Orange Book and in suing counterplaintiffs for infringement of the '491 patent, counterplaintiffs are presently prevented from selling alfuzosin hydrochloride extended release tablets and are being

injured as a result. Counterplaintiffs seek patent certainty with respect to the '491 and '940 patents and certainty regarding the legal rights relating to Apotex, Inc.'s ANDA through a judicial declaration that the '491 and '940 patents are not infringed by the alfuzosin hydrochloride extended release tablets identified in Apotex, Inc.'s ANDA, or that the patents are invalid.

22. A real, actual, and justiciable controversy exists between counterplaintiffs and Sanofi regarding the invalidity of the '491 and '940 patents and counterplaintiffs' non-infringement thereof, constituting a case of actual controversy within the jurisdiction of this Court under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

COUNT I
(Declaration of Non-Infringement of the '491 Patent)

23. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-22.

24. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

25. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent.

COUNT II
(Declaration of Invalidity of the '491 Patent)

26. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-25.

27. The claims of the '491 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

28. Counterplaintiffs are entitled to a declaration that the claims of the '491 patent are invalid.

COUNT III
(Declaration of Non-infringement of the '940 Patent)

29. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-28.

30. The manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

31. Counterplaintiffs are entitled to a declaration that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent.

COUNT IV
(Declaration of Invalidity of the '940 Patent)

32. Counterplaintiffs reallege and incorporate by reference the allegations of Paragraphs 1-31.

33. The claims of the '940 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112.

34. Counterplaintiffs are entitled to a declaration that the claims of the '940 patent are invalid.

REQUEST FOR RELIEF

WHEREFORE, Defendants Apotex Inc. and Apotex Corp. respectfully request that this Court enter a Judgment and Order in its favor and against Plaintiffs Sanofi-Aventis and Sanofi-Aventis US as follows:

(a) Declaring that the manufacture, use, sale, offer for sale or importation into the United States of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '491 patent;

(b) Declaring that the claims of the '491 patent are invalid;

(c) Declaring that the manufacture, use, or sale of the alfuzosin hydrochloride extended release tablets, 10 mg, that are the subject of Apotex Inc.'s ANDA No. 79-013 have not infringed, do not infringe, and would not, if marketed, infringe any valid or enforceable claim of the '940 patent;

(d) Declaring that the claims of the '940 patent are invalid;

(e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding counterplaintiffs their attorneys' fees, costs, and expenses in this action; and

(f) Awarding counterplaintiffs any further and additional relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Apotex, Inc. and Apotex Corp. demand trial by jury for all issues triable by jury as a matter of right.

DATED: January 2, 2008
Miami, FL

Respectfully submitted,

s/. Stephen J. Bronis
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Attorneys for Apotex Corp. and Apotex, Inc.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing served by mail on January 2, 2008 on all counsel of record on the attached service list.

s/. Jennifer Coberly
Jennifer Coberly

SERVICE LIST
Case No. 07-61800-CIV-MORENO/SIMONTON

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Sanofi-Aventis and Sanofi-Aventis, U.S. LLC

EXHIBIT C

UNITED STATES DISTRICT COURT FOR THE
SOUTHERN DISTRICT OF FLORIDA
Miami Division

Case Number: 07-61800-CIV-MORENO

SANOFI-AVENTIS and SANOFI-AVENTIS U.S. LLC,

Plaintiffs,

vs.

APOTEX INC. and APOTEX CORP.,

Defendants.
_____/

ORDER OF CONTINUANCE AND ORDER REVISING PRETRIAL DEADLINES

THIS CAUSE came before the Court upon Plaintiffs' Motion to Continue Pretrial Deadlines and Trial **(D.E. No. 12)**, filed on **January 15, 2008**.

THE COURT has considered the motion and the pertinent portions of the record, and being otherwise fully advised in the premises, it is

ADJUDGED that for good cause shown, the motion is **GRANTED** as follows.

(1) TRIAL DATE - The trial is **CONTINUED** from the two-week period of **May 27, 2008**, to the two-week period of **October 6, 2008**, in Miami, Florida.

(2) CALENDAR CALL - Counsel must appear at Calendar Call which shall take place before the undersigned at the United States Courthouse, Federal Justice Building, Courtroom IV, Tenth Floor, 99 Northeast 4th Street, Miami, Florida 33132, on **Tuesday, September 30, 2008, at 2:00 P.M.** The parties need not appear at Calendar Call. At Calendar Call counsel may bring all matters relating to the scheduled trial date to the attention of the Court.

(3) PLAINTIFF'S WITNESS AND EXHIBIT LISTS - Plaintiff shall provide

Defendant, by either fax or hand delivery, a copy of Plaintiff's Witness List and a copy of Plaintiff's Exhibit List no later than **Wednesday, September 17, 2008, at 5:00 P.M.**

(a) PLAINTIFF'S WITNESS LIST - Plaintiff's Witness List shall include all the witnesses, both lay and expert, that Plaintiff intends to call at trial. Plaintiff's Witness List shall briefly describe the nature of each witness's testimony and whether such witness will be testifying live or by deposition. Witnesses omitted from the list will not be allowed at trial.

(b) PLAINTIFF'S EXHIBIT LIST - Plaintiff's Exhibit List shall include all the exhibits that Plaintiff intends to use at trial. Plaintiff's Exhibit List shall in consecutively numbered paragraphs adequately describe the nature of each document listed. The actual exhibits shall be pre-marked with corresponding numbers (*e.g.* Plaintiff's Exhibit #1, P.E. #2, P.E. #3...) which numbers they will retain through the end of trial. The exhibit list shall refer to specific items and shall not include blanket statements such as *all exhibits produced during depositions* or *Plaintiff reserves the use of any other relevant evidence.* Exhibits omitted from the list will not be allowed at trial.

(4) DEFENDANT'S WITNESS AND EXHIBIT LISTS - Defendant shall provide Plaintiff, by either fax or hand delivery, a copy of Defendant's Witness List and a copy of Defendant's Exhibit List no later than **Friday, September 19, 2008, at 5:00 P.M.**

(a) DEFENDANT'S WITNESS LIST - Defendant's Witness List shall include only those additional lay and expert witnesses not included on Plaintiff's Witness List. Witnesses listed by Plaintiff will be available for both parties and should not

be re-listed on Defendant's Witness List. Defendant's Witness List shall briefly describe the nature of each additional witness's testimony and whether such witnesses will be testifying live or by deposition. Witnesses omitted from Defendant's Witness List and not listed on Plaintiff's Witness List will not be allowed at trial.

(b) DEFENDANT'S EXHIBIT LIST - Defendant's Exhibit List shall include only those additional exhibits that Defendant wishes to introduce at trial which are not on Plaintiff's Exhibit List. Defendant's Exhibit List shall in consecutively numbered paragraphs adequately describe the nature of each document listed. The actual exhibits shall be pre-marked with corresponding numbers (*e.g.* Defendant's Exhibit #1, D.E. #2, D.E. #3...) which numbers they will retain through the end of trial. The exhibit list shall refer to specific items and shall not include blanket statements such as *all exhibits produced during depositions* or *Plaintiff reserves the use of any other relevant evidence.* Exhibits omitted from Defendant's Exhibit List and not listed on Plaintiff's Exhibit List will not be allowed at trial.

(5) PRETRIAL STIPULATION - Pursuant to S.D. Fla. L.R. 16.1.E., the parties shall file a Pretrial Stipulation no later than **Tuesday, September 23, 2008**. The Pretrial Stipulation shall conform to the requirements of S.D. Fla. L.R. 16.1.E. The parties shall attach to the Pretrial Stipulation copies of the witness and exhibit lists along with any objections as allowed for under S.D. Fla. L.R. 16.1.E.9.

(6) OTHER PRETRIAL DEADLINES -

(a) Discovery - The parties shall complete all expert and non-expert discovery no later than **August 6, 2008**.

(b) Summary Judgment - The parties shall file all motions for summary judgment no later than **August 20, 2008**.

(c) Pretrial Motions - The parties shall file all other pretrial motions no later than **September 5, 2008**.

(7) PREVIOUS SCHEDULING ORDERS - This Order shall supercede only the inconsistent provisions of previous Scheduling Orders.

DONE AND ORDERED in Chambers at Miami, Florida, this 22nd day of January, 2008.

FEDERICO A. MORENO
UNITED STATES DISTRICT JUDGE

Copies provided to:

Parties and Counsel of Record

EXHIBIT D

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CHAMBERS OF
HAROLD A. ACKERMAN
SENIOR JUDGE

UNITED STATES DISTRICT COURT
POST OFFICE BOX 999
NEWARK, NEW JERSEY 07101-0999

November 16, 2006

TO ALL COUNSEL OF RECORD

Re: *Adams Respiratory Therapeutics, Inc. v. Mutual Pharm. Holdings Co.*, Civil Action No. 06-4700

Dear Counsel:

I have reviewed the letters from counsel regarding Plaintiff's request that this Court hold an immediate status conference "to resolve issues relating to an identical case pending in the Eastern District of Pennsylvania." (Pl.'s Letter to Court 11/9/06 at 1.) After careful consideration, this Court denies Plaintiff's request.

Plaintiff Adams Respiratory Therapeutics, Inc. ("Adams") filed the instant action in this Court on October 2, 2006. Prior to filing its Complaint in this Court, Adams learned that Defendant Mutual Pharmaceutical Holdings, Co. ("Mutual") had challenged this Court's personal jurisdiction in an unrelated case, *Eisai Co., Ltd. v. Mutual Pharmaceutical*, Civ. No. 06-3613 (D.N.J. filed August 3, 2006). As Adams notes, Eisai's response to Mutual's personal jurisdiction challenge has been stayed pending jurisdictional discovery.

Understandably concerned that a successful challenge to the personal jurisdiction of this Court by Mutual in the *Eisai* action conceivably could cause Adams problems in its own suit against Mutual, Adams filed an identical action in the Eastern District of Pennsylvania two days after filing in this Court. This was necessary, from Adams's viewpoint, to preserve "certain substantive rights provided under the Hatch-Waxman Act." (Pl.'s Letter to Court 11/9/06 at 2.) Subsequent to filing in Pennsylvania, Adams moved that court to stay proceedings there pending the outcome of the jurisdictional issue in this Court. The Eastern District of Pennsylvania denied the motion to stay and the case is proceeding apace in that District.

Adams requests that I exercise my discretion as the Court in which the first action was filed and enjoin the Eastern District of Pennsylvania from proceeding with the case filed in that jurisdiction. (Pl.'s Letter to Court 11/9/06 at 3 (citing *Triangle Conduit & Cable, Inc. v. National Electric Prod. Corp.*, 125 F.2d 1008, 1009-10 (3d Cir. 1942); *Crosley Corp. v. Hazeltine Corp.*, 122 F.2d 925, 929 (3d Cir. 1941)).) While I recognize that I have the power to direct the Eastern District of Pennsylvania to stay its related, subsequently-filed proceeding, I decline to exercise that power.

The "first-filed rule" is intended to prevent duplicative litigation, but I do not believe the rule was intended to provide a single plaintiff the opportunity to institute identical suits in various jurisdictions and then put all but the first one on the back burner until such time as the plaintiff deems convenient. *See Triangle*, 125 F.2d at 1008-09 (reversing district court of first-filed case for not enjoining second case filed by *defendant* in another district).

Presumably, Adams would like me to decide the *Eisai v. Mutual* personal jurisdiction issue, which would give Adams some indication of whether it would prevail on the same issue, especially now that Mutual has raised the same personal jurisdiction issue in the *Adams v. Mutual* case as well. If Adams were satisfied with my ruling in the *Eisai v. Mutual* case, then, ostensibly, it would voluntarily dismiss the Pennsylvania action and proceed with its identical case in this Court. Alternatively, now that Mutual has moved this Court to dismiss for lack of personal jurisdiction, it would be of great benefit to Adams if I decided that motion out of turn.

With respect to the *Eisai v. Mutual* motion, I cannot decide a motion that has not been fully briefed and that is stayed pending jurisdictional discovery. With respect to the more recently filed motion by Mutual in this case, I am disinclined to make any decision of such importance in haste. Moreover, as I am sure counsel can appreciate, my docket contains many other motions that were filed well in advance of this one that are of equal importance to the respective parties. While I am sympathetic to Adams's predicament, the situation is of its own making. If Adams wants to proceed in its first choice of forum, it knows how to unilaterally effectuate that circumstance.

This Court hereby DENIES Adams's request for an immediate status conference and hereby DENIES Adams's request that this Court enjoin the Eastern District of Pennsylvania action.

SO ORDERED

s/ Harold A. Ackerman
U.S.D.J.

HAA:amb

EXHIBIT E

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ADAMS RESPIRATORY THERAPEUTICS, INC.	:	**CIVIL ACTION**
Plaintiff,	:	
	:	
v.	:	**NO. 06-4418**
	:	
PHARMACEUTICAL HOLDINGS CORP., et al.	:	
Defendants	:	
	:	

ORDER

AND NOW, this 2nd day of November, 2006, it is **ORDERED** as follows:

1. Plaintiff's Motion to Stay (Doc. No. 18), filed on October 24, 2006, is **DENIED**. Plaintiff brings this action under the Hatch-Waxman Act, asking me to conclude that Defendants' intended manufacture and sale of a generic drug would violate Plaintiff's patent for the drug "Mucinex." See 21 U.S.C. § 355(j)(5)(B)(iii). Plaintiff filed the instant Complaint only two days after filing a nearly-identical Complaint in the District of New Jersey. Adams Respiratory Therapeutics, Inc. v. Pharmaceutical Holdings Corp., Civ. Action No. 2:06-cv-04700-HAA-MF (D. N.J., filed October 2, 2006). Defendants have disputed jurisdiction in New Jersey, but concede that jurisdiction exists here. Plaintiff has explained that it filed in this Court so that it will have a "back-up" forum in the unlikely event that the New Jersey Court determines after Plaintiff's statutory forty-five day window has elapsed that the District of New Jersey is without jurisdiction to hear Plaintiff's first-filed action. See 21 U.S.C. § 355(j)(5)(B)(iii) (to stay FDA final approval of generic drug application, patent owner must bring suit within forty-five days of receiving notice that generic drug applicant has filed a certification that the patent is invalid or

not infringed). Plaintiff now seeks a stay of the instant matter, pending the New Jersey Court's decision on jurisdiction. Should that Court determine it is without jurisdiction, Plaintiff would then seek to proceed against Defendants in this Court.

Defendants vigorously contend that Plaintiff seeks a stay solely for delay, so that Plaintiff can take advantage of Hatch-Waxman's thirty month non-compete period. See id. (if patent owner files suit within forty-five day window, FDA will place a thirty-month automatic stay on approval of generic drug application, unless the Court issues a decision before expiration of thirty-month period). Plaintiff responds with equal vigor that Defendants have filed an Answer, Counterclaim, and Summary Judgment Motion (before Plaintiff even served the instant Complaint) to create the false impression that the action before me is well on its way to conclusion.

Without impugning the motives of Plaintiff or Defendants, I believe granting a stay here would encourage judge-shopping. I do not believe the "first-filed" rule – on which Plaintiff almost exclusively relies – applies in the unique circumstances presented here. The decisions Plaintiff has cited – in which the "first-filed" rule is applied – are inapposite. See Semmes Motors, Inc. v. Ford Motor Co., 429 F.2d 1197 (2d Cir. 1970) (plaintiff filed two cases in different districts, and defendant moved to stay); Old Charter Distillery Co. v. Continental Distilling Corp., 59 F. Supp. 528 (D. Del. 1945) (plaintiff filed two cases in different districts, and second court granted plaintiff's motion to stay after first court ruled that it had jurisdiction). I believe it would be inappropriate to allow a plaintiff to file identical actions in different courts and then pick the court in which it wishes to proceed while the other action is stayed pending the result in the first-filed action. Plaintiff has chosen to sue here; it can not credibly complain that proceeding with this suit is prejudicial. Accordingly, I will deny the Motion to Stay.

2. Defendants' Motion for Summary Judgment (Doc. No. 10), filed on October 17, 2006, is **DENIED WITHOUT PREJUDICE** because it is premature. Defendants are free to renew their Motion at the close of discovery or at another appropriate time.

3. Defendants' Motion for Leave to File Trade Secrets and Confidential Business Information Under Seal (Doc. No. 11), filed on October 17, 2006, is **GRANTED**.

4. The Declarations of Harry G. Brittain and Robert Dettery, along with the attached exhibits, shall be maintained under seal and shall not be made available to the public, except as provided by subsequent Order of this Court.

5. Defendants shall file, as soon as practicable, a public record version of the Declarations of Harry G. Brittain and Roberty Dettery with redactions of the portions of the declarations that contain the trade secret and confidential business information.

6. Defendants' Counterclaim (Doc. No. 4), filed on October 10, 2006, appears to turn entirely on the viability of Plaintiff's patent. Accordingly, resolution of the merits of Plaintiff's Complaint should precede resolution of the Counterclaim. Thus, Defendants' Counterclaim is **STAYED** pending resolution of the Plaintiff's claims.

IT IS SO ORDERED.

/s Paul S. Diamond, J.

Paul S. Diamond, J.